

Remarks

## I. Claims Status

Prior to this amendment, claims 1-12 were pending. Claims 2-8, 11 and 12 have been cancelled without prejudice. Claim 1 has been amended to restrict R<sup>1</sup> to quinazoline and substituted quinazoline, and restrict R<sup>3</sup> and R<sup>6</sup> to non-heterocyclic groups. Additionally no longer required proviso language has been deleted. Support for R<sup>1</sup> being a quinazoline group is found in the specification application as filed in original claim 5 and page 35 lines 20-23.

New claims 13 and 14 have been added. Claim 13 is directed to the compound in Example 3 or a pharmaceutically acceptable salt thereof. Support may be found in the application as filed at page 25 lines 20-23, page 23 lines 1-31, page 24 lines 1-14. Claim 14 is directed to a pharmaceutical composition comprising the compound in Example 3 or a pharmaceutically acceptable salt thereof. Support may be found in the application as filed at page 25 lines 20-23 and page 14 lines 11-12.

No new matter has been added by these amendments.

## II. Claim Rejections

## a) 35 U.S.C. § 112 First Paragraph

Claim 1 stands rejected under 35 U.S.C. § 112 first paragraph. The Examiner contends that the prodrugs and solvates of the compounds of the invention are not enabled. Applicants respectfully traverse this rejection. Applicants submit that prodrugs and solvates of the compounds of the invention are enabled and have been generally described. The test for enablement is whether one reasonably skilled in the art could make and use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Applicants submit that based on this extensive teaching of the present specification a person of ordinary skill in the art can readily select any number of appropriate prodrug moieties to form prodrugs of the compounds of the invention, or in the case of solvates, recrystallization or chromatographic solvents to form solvates of the compounds of the invention upon recrystallization or evaporation. Applicants specifically point to the specification as filed at page 29 lines 3-31 and page 33 lines 1-5 for description of various prodrugs. It is contended that one of reasonable skill would be able to choose prodrug moieties compatible with the structure of the compound of the invention based on the

information in the specification and information known in the art without undue experimentation.

The Examiner in analyzing the Wands factors appears to be basing a significant part of her argument on stability and interconversion of one form into another (either prodrug or solvate) during manufacture. Applicants respectfully argue that the Examiners analysis is misplaced. In order for a prodrug to fulfill its intended function it would have to be stable to most conditions except for metabolism in the body as pointed out in the specification at page 29 lines 5-19. The prodrug moieties taught in the specification coupled with what is known in the art would enable one of reasonable skill to synthesize prodrugs that are stable except for metabolism in the body.

Solvates are crystalline or amorphous forms of compounds where solvent molecules have been trapped within the crystalline lattice structure or within the amorphous solid. Solvent molecules may in some cases be driven off upon standing, heating or under reduced pressure or a combination of heating and reduced pressure. The formation of solvates requires only some solubility of the compound in a solvent followed by recrystallization or reduction in vacuo. It is therefore contended that given the teaching of the specification coupled with what is known in the art would enable one of reasonable skill to synthesize solvates. The long or short term stability of the solvate or its stability during manufacture of the formulated drug is not relevant to the question of enablement.

Applicants respectfully request reconsideration and withdrawal of this rejection.

b) 35 U.S.C. § 112 Second Paragraph

Claim 1 stands rejected under 35 U.S.C. § 112 second paragraph. The Examiner contends that the terms “prodrug” and “solvate” in claim 1 are indefinite. Applicants respectfully traverse this rejection. The test for indefiniteness is whether those skilled in the art would understand what is being claimed. The term “prodrug” is a known term of art which is defined in the specification at page 29 line 5-12. Solvates are a known term of art which is defined as a crystalline or amorphous form of a compound which contain a certain amount of a solvent. It is therefore contended that one of reasonable skill would know and

understand what is being claimed and therefore the terms are not indefinite. Reconsideration and withdrawal of this rejection is respectfully requested.



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Conclusion

It is believed that the application is now in condition for allowance. Favorable action is earnestly solicited. If the Examiner believes a telephonic interview would expedite the prosecution of the instant case she is invited to call the applicants representative whose contact information appears below.

Please charge the \$130.00 fee due under 37 C.F.R. §1.20(d) to Deposit Account No.16-1445. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two (2) copies of this sheet are enclosed herewith.

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Nicholas J. Sisti, Ph.D., J.D.  
Senior Patent Agent  
Reg. No. 54,453

Pfizer Inc  
Patent Department  
Eastern Point Road, MS8260-1611  
Groton, Connecticut 06340  
(860) 686-2883